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09/583,848

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

13

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/583,848

Applicant(s)

GAUGLER ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 54-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 37-53 and adds new claims 54-67 which are related to claims 37-53.

It is noted that the claims 48-50 on page 3 of the response of paper No:12 have been cancelled and are not considered.

Accordingly, claims 54-67 are being examined.

The following are the remaining rejections.

Applicant asserts that claims 54-67 parallel claims found allowable in SN=09/583,850 and SN=09/597179. Applicant asserts that any Office action that follows that rejects claims without including complete discussion of why the Examiner, who is in the same art unit as the Examiners who allowed the prior cases, is differing from art unit practice.

It is noted that different cases drawing to different sequences to be examined are different and could not be applied to the instant application. It is further noted that case SN=09/597179 drawn to HIGH PERFORMANCE COIL WIRE is not even remotely applicable to the instant application.

### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER**

Claim 58 is rejected under 35 USC 112, first paragraph pertaining to new matter remains for reasons already of record for previous claim 41 in paper No.11.

Rejection remains because Applicant does not point out pages and lines in the specification that support the claim.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claims 54-58, 60-67 are rejected under 35 USC 112, first paragraph pertaining to lack of a clear description remains for reasons already of record for previous claims 37-41, 43-47 in paper No.11.

Applicant argues that the *Lilly* case is not relevant here. Different from *Lilly* case, SEQ ID NO:18 is presented. With respect to the "complement" language, the application as a whole states that tumor rejection antigen precursors are molecule large enough to be processed to smaller ones. The claims are drawn to molecules which encode such larger molecules. Applicant argues that the Examiner's position is diametric to the guidelines which the Examiner is supposed to follow. Applicant refers to a copy of Example 9, stating that it is "on all fours" with the claims.

Applicant submits the reference by De Plaen et al, Immunogenetics, 1994, 40: 360-369, which teaches MAGE-6, which is expressed in tumors, and not in normal tissues, except testis. Applicant further submits the references by Zorn, E et al, 1999, Eur J Immunol, 29: 602-607, Tanzarella, S et al, 1999, Cancer Res, 59: 2668-2673, Tatesumi et al, 2002, J exp Med, 196(5): 619-628, as well as US 5,928,938, US 6,265,215, and 6,323,028, asserting that the MAGE-6 molecule is expressed as a protein, which is then processed to peptides (tumor rejection antigens).

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The submission of the references by De Plaen et al, Immunogenetics, 1994, Zorn, E et al, 1999, Tanzarella, S et al, 1999, Tatesumi et al, 2002, US 5,928,938, US 6,265,215, and 6,323,028 is acknowledged.

Applicant's arguments set forth in paper No.12 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that claims 54, 56-57, and dependent claims 60, 62, 64, 65, 67 encompass full length nucleic acid sequences of any length encompassing SEQ ID NO:18, having 225 base pairs, which is only a small fragment of full length MAGE-6 mRNA or gene, of which the largest open reading frame of the last exon has 1043 nucleotides, as disclosed De Plaen et al, Immunogenetics, 1994, 40: 360-369, figures 1 and 2, submitted by Applicant in the response. Similarly, claims 55 and dependent claims 63, 66 encompass nucleic acid sequences of any length, encompassing fragments of MAGE-6 mRNA or gene, of which the largest open reading frame of the last exon has 1043 nucleotides. In addition, claim 58 and dependent claims 61, encompass a cDNA molecule encoding a fragment of MAGE-6, wherein said fragment is processed by cells to a tumor rejection antigen, i.e. inducing CTL lysis.

The structure of these claimed sequences however are not disclosed in the specification, nor incorporated into the specification by references.

Further, It is not clear that the nucleic acid fragment of 225 nucleotides of SEQ ID NO:18 encodes any "tumor rejection antigen", i.e. peptide fragments that could induce specific CTL lysis, since not any region of a protein antigen, such as MAGE-6, would induce CTLs response (Roitt et al, of record), and since the MAG-6 fragments that could

induce CTL lysis, as identified by Zorn, E et al, 1999, Eur J Immunol, 29: 602-607, Tanzarella, S et al, 1999, Cancer Res, 59: 2668-2673 (submitted by Applicant in the response) do not seem to be encoded by a polynucleotide sequence within the 225 nucleotides of SEQ ID NO:18.

Thus the claimed SEQ ID NO:18 does not seem to encode a tumor rejection antigen precursor or a tumor rejection antigen, which could induce CTLs lysis, and thus this language as disclosed in the specification could not be applied as a functional language for the claimed SEQ ID NO:18.

Moreover, Example 9 does not disclose the structure or function of the claimed sequences.

In view of the above, i.e no structure, nor function of the claimed sequences are disclosed in the specification and the claims, the Lilly case is clearly relevant, since the court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus the claims 54-58, 60-67 remain rejected under 112, first paragraph, written description.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE**

Claims 54-67 are rejected under 35 USC 112, first paragraph pertaining to lack of enablement for a nucleic acid molecule "encoding" a tumor rejection antigen precursor or a tumor rejection antigen, or fragment thereof, remains for reasons already of record for previous claims 37-47 in paper No.11.

Applicant submits the references by Zorn, E et al, 1999, Eur J Immunol, 29: 602-607, Tanzarella, S et al, 1999, Cancer Res, 59: 2668-2673, Tatesumi et al, 2002, J exp Med, 196(5): 619-628, as well as US 5,928,938, US 6,265,215, and 6,323,028, asserting that the MAGE-6 molecule is expressed as a protein, which is then processed to peptides (tumor rejection antigens).

The submission of the references by Zorn, E et al, 1999, Tanzarella, S et al, 1999, Tatesumi et al, 2002, US 5,928,938, US 6,265,215, and 6,323,028 is acknowledged.

Applicant's arguments set forth in paper No.12 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that the claims encompass a nucleic acid molecule fully complementary to SEQ ID NO:18 and thus having 225 nucleotides.

It is unpredictable that the nucleic acid fragment of 225 nucleotides of SEQ ID NO:18 encodes any "tumor rejection antigen", i.e. peptide fragments that could induce specific CTL lysis, since not any region of a protein antigen, such as MAGE-6, would induce CTLs response (Roitt et al, of record), and since the MAGE-6 fragments that could induce CTL lysis, as identified by Zorn, E et al, 1999, Eur J Immunol, 29: 602-607,

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Tanzarella, S et al, 1999, Cancer Res, 59: 2668-2673 (submitted by Applicant in the response) do not seem to be encoded by a polynucleotide sequence within the 225 nucleotides of SEQ ID NO:18.

## **REJECTION UNDER 35 USC 102**

Claim 55 is rejected under 35 USC 102(b) pertaining to anticipation by Kudo et al remains for reasons already of record for previous claim 38 in paper No.11.

Applicant argues that the art recited by the Examiner consists of 10 nucleotides. At most this could encode three amino acids. As explained in the specification tumor rejection antigens are at least 8 amino acid long, encoded by at least 24 nucleotides. Fragments of tumor rejection antigen precursor are larger than this. Hence a 10 nucleotide stretch does not meet the claim. Applicant also would know where the start codon is in the cited art.

Applicant's arguments set forth in paper No.12 have been considered but are not deemed to be persuasive for the following reasons:

The cited sequence taught by Kudo et al meet all the limitation of the claim. It is noted that a fragment could be as little as two amino acids. There is no limitation in the claim nor definition in the specification reciting that the claimed fragment of a tumor rejection antigen precursor has to be at least 8 amino acids long. Applicant is invited to submit evidence pointing to the page and line where support can be found establishing that a fragment of a tumor rejection antigen precursor has to be at least 8 amino acids long.



Concerning the start codon of the cited art, the start codon of the cited art is not relevant, because the specification does not teach where the start codon of the claimed SEQ ID NO:18 is.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

February 20, 2003

  
SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER